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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,932	07/21/2005	Sadanobu Shirai	2005-1129A	9214
513 7590 12/05/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 12/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,932	<b>Applicant(s)</b> SHIRAI, SADANOBU	
	<b>Examiner</b> Melissa S. Mercier	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7, 10, 12, 17, 18, 20 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8, 9, 11, 13-16, 19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of Applicants Remarks and Amended Claims filed on October 1, 2007 is acknowledged. Claims 1-24 are pending in this application. Claims 1-2, 4-6, 8-9, 11, 13-16, 19, 21-23 are under prosecution in the application. Claims 3, 7, 10, 12, 17-18, 20, and 24 remain withdrawn from consideration. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently

distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes a species of the instantly claimed cellulose derivatives at p. 9, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by cellulose derivatives.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues. Applicant respectfully submits that the Examiner has not presented any "evidence or reasons" why the art-skilled would not recognize in the disclosure a description of the invention defined by the claims. Rather, the Examiner has merely stated that the specification does not describe a sufficient number of species as to convey possession of the entire genus encompassed by cellulose derivatives. This is not "evidence or reasons" to support the rejection. Furthermore, Applicant takes the position that in view of the species disclosure on page 9 and in Examples 1-4, combined with the generic term "a cellulose derivative", one of ordinary skill in the art would recognize that Applicant indeed had possession of the claimed invention. The examiner disagrees. Applicant has defined the generic term cellulose derivative by listing 3 derivatives and so on. The term "so on" does not provide adequate written description for the entire genus of cellulose derivative.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 5-6, 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (US Patent 6,221,382).

Ishida discloses a sheet pack having a multilayer moisture permeable support including a hydrophobic layer and a hydrophilic layer (abstract). The material applicable to the multilayer support is a fabric or a laminate of a fabric and a film. The material of the hydrophobic may be comprised of polyethylene (column 4, lines 30-35). The hydrophilic layer may be comprises of a natural fiber such as cotton. A mixture of a hydrophilic fiber with a hydrophobic fiber such as polypropylene or polyethylene may be used (column 4, lines 35-45). Methods for the lamination of the fabric and film include thermally laminating a fabric and a resin film which has been previously dissolved in a solvent or thermally molten (column 7, lines 30-36). Example 1 further discloses the method of making the sheet pack and discloses a cosmetic substance impregnating the sheet having a water content of 17-19% by weight (column 10, lines 1-50).

Ishida does not disclose the weight of the adhesive layer laminated on the support.

The instant claims differ from the references only in the specific weight of the adhesive layer. However, it would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the amount of the adhesive layer utilized in order to provide a cataplasm with the desired properties in

order to provide the optimum therapeutic effect. Therefore, it is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as a whole has been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues the invention of Ishida et al. relates to a peel-off-type sheet -pack having a multi-layer moisture-permeable support including a hydrophobic layer and a hydrophilic layer, and a cosmetic. The object of Ishida et al. is to provide an improved peel-off-type pack which does not have a sticky surface, completes the formation of film in a relatively short period of time, is not easily torn in the course of peeling off, and does not leave remains of the film on the surface of the skin (Column 2, lines 30-35); and In addition Ishida et al. disclose "The sheet pack of the present invention has the hydrophobic layer of the multi-layer moisture-permeable support on its surface, which is accordingly not sticky." (Column 3, lines 15-18, emphasis added). The "surface" obviously means the part not containing the cosmetic and contacting to the open air. Applicant is arguing claim limitations which are not present in the instant claims. The claim language used does not exclude a peel off type sheet. The examiner points out; a mixture of hydrophilic fiber with a hydrophobic fiber may be used. It is the examiner's position that this "mixture" would include entanglement. Additionally, Ishida discloses sintering of the resin, which would include heat fusing.

Claims 4, 8-9, 13, 15, 19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (US Patent 6,221,382), in view of Misumi et al (US Patent 6,224,899).

The teaching of Ishida are discussed above and applied in the same manner.

Ishida does not disclose the composition of the adhesive layer.

Misumi discloses a composition comprises a polyacrylic acid compound, a polyvalent metal component and water, wherein the content of water is 75 to 95% by weight. Also disclosed are an adhesive cooling composition shaped into a sheet (abstract). The amount of polyacrylic acid present is 1-20% by weight (column 3, lines 50-51). Suitable examples of the polyvalent metal component are aluminum, including aluminum hydroxide (column 3, line 53- column 6, line 2). The amount of polyvalent metal compound is 0.01-20% by weight (column 4, lines 16-17). The adhesive cooling composition may further contain a polyhydric alcohol, such as glycerin, propylene glycol, and butylenes glycol (column 5, lines 9-25). The amount of polyhydric alcohol can be 0.001-30% by weight (column 5, lines 26-27). Additionally, an acid may be added to the adhesive composition to adjust the pH of the composition (column 4, line 66-column 5, line 1).

The instant claims differ from the references only in the specific weight of the water present in the adhesive layer. However, it would have been deemed *prima Facie* obvious to one having ordinary skill in the art at the time of the invention to optimize the amount of the adhesive layer utilized in order to provide a cataplasm with the desired

properties in order to provide the optimum therapeutic effect. Therefore, it is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Furthermore, It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that patches would comprise adhesive layers, for application of compositions to the skin, it would have been obvious to combine these adhesives with the expectation that such a combination would be effective. Thus, combining them flows logically from their having been individually taught in prior art.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments regarding the Ishida reference are discussed above. Applicant did not submit any additional arguments regarding the Misumi reference.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

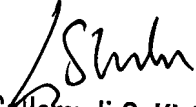
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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